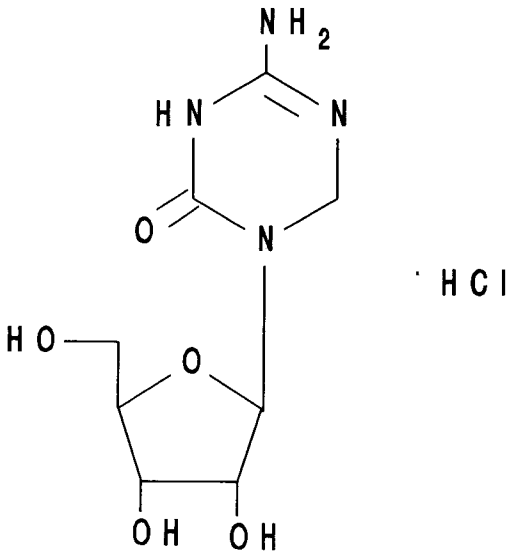
DIHYDRO-5-AZACYTIDINE

NSC - 264880



Chemical Name: 4-Amino-3,6-dihydro-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one, monohydrochloride

Other Names: DHAC

CAS Registry Number: 62402-31-7

Molecular Formula: $C_8H_{14}N_4O_5 \cdot HCl$ **M.W.:** 282.7

How Supplied: For Injection, 500 mg, vial: supplied as a white lyophilized powder with 300 mg of mannitol, USP, in a 20 mL flint vial.

Solution Preparation: 500 mg/vial: When constituted with 9.6 mL of Sterile Water for Injection, USP, each milliliter contains 50 mg of dihydro-5-azacytidine HCl and 30 mg of mannitol at pH 3.0 to 5.0.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at room temperature (22-25 °C), at least one year at elevated temperature (50 °C).

Solutions of dihydro-5-azacytidine HCl are stable over a pH range of 3 to 8. A study of dihydro-5-azacytidine HCl 3.75 mg/mL in buffer solutions with pH values varying from 3 to 8 stored at 50 °C showed 2 to 3% decomposition in 2 days at all pH values.

When constituted as directed, dihydro-5-azacytidine HCl solutions exhibit little or no decomposition over 24 hours at room temperature.

Further dilution to a concentration of 0.5 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP, and in Lactated Ringer's Injection, USP, results in solutions which exhibit 1 to 2% decomposition over 2 days at room temperature.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous